Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Headquarters

AL05-10 May 12, 2005

Item: CM 100-Heartstart Adapter Cable manufactured by Laerdal Medical Corporation, for use with various make/model defibrillators.

Specific Incident: Laerdal Medical Corporation is voluntarily recalling all lots of CM 100-Heartstart Adapter Cable; catalogue no. 920650, because wires within this adapter cable are susceptible to breakage. The vendor reports failure to deliver defibrillation shocks when there is breakage in this cable.

This adapter cable allows Laerdal Heartstart brand defibrillation electrodes with snap connectors to be used with HP/Agilent/Philips CodeMaster 100 and CodeMaster SL+/XL/XE defibrillators, Laerdal Heartstart 4000 defibrillators, and Philips HeartStart XLT, HeartStart XL and HeartStart MRx defibrillators.

Action:
1. Immediately (within the next 24 hours) remove CM 100-Heartstart Adapter Cable from service and inventory.
2. Assure replacement cable from another source is available for each defibrillator where the cable was removed.

Addl. Information: Cable description: A 26 inch long black colored “Y” configuration cable assembly with one cylindrical white two-pole connector at its base and a patient electrode snap connector on each of the two remaining leads, one red and one white. The number 281-132-00 appears on a white label band affixed to one of the leads.

Source: Laerdal Medical Corporation (see attached notification)
FDA

Contact: Laerdal National Notification Center at 1-800-668-4391

FOR IMMEDIATE RELEASE:

Contact:
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Date: April 28, 2005

Laerdal Medical Announces Voluntary Nationwide Recall of Adapter Cable for Certain Defibrillators

FOR IMMEDIATE RELEASE – Wappingers Falls, NY – April 28, 2005 – Laerdal Medical Corporation, Wappingers Falls, New York, a subsidiary of Laerdal Medical AS, Stavanger, Norway, today announced that it is voluntarily recalling all lots of **CM 100-Heartstart Adapter Cable, Cat. No. 920650** (Adapter Cable). Wires within the defibrillator adapter cables are susceptible to breakage.

Laerdal has received reports regarding incidents of wire breakage in the Adapter Cable that prevented delivery of defibrillation shocks. The test method described in the defibrillator instructions for use will not detect internal breaks in the adapter cables. Use of these Adapter Cables should be discontinued.

The Adapter Cable allows Laerdal Heartstart brand defibrillation electrodes with snap connecter to be used with HP/Agilent/Philips CodeMaster 100 and CodeMaster SL+/XL/XE defibrillators, Laerdal Heartstart 4000 defibrillators, and Philips HeartStart XLT, HeartStart XL, HeartStart MRx defibrillators.

The Adapter Cable was supplied as a standard accessory with most CodeMaster 100 defibrillators that Laerdal distributed, and was sold as an optional accessory for use with the Laerdal Heartstart 4000 automated external defibrillator (AED).

Cable Description: A 26" long black-colored "Y" configuration cable assembly with one cylindrical white two-pole connecter at its base, and a patient electrode snap connector on each of the two remaining leads, one red and one white. The number 281-132-00 appears on a white label band affixed to one of the leads.

Over 3,000 Adapter Cables have been sold throughout the U.S. since 1996.

Replacement cables from Laerdal are not available. Compatible alternative cabled electrodes that do not require adapters are available from Philips Medical Systems.

This recall is being conducted with the full knowledge of the US Food and Drug Administration (FDA), and is being facilitated for Laerdal by the National Notification Center (NNC), a professional recall contractor. Consumers with questions about the recall should contact NNC at 1-800-668-4391. Other inquiries should be addressed to Laerdal at 1-877-523-7325, or customerservice@laerdal.com.

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